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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/600,564	11/07/2000	Florian Kern	KREISLER1089	5234
27384	7590	09/22/2004	EXAMINER	
NORRIS, MCLAUGHLIN & MARCUS, PA 875 THIRD STREET 18TH FLOOR NEW YORK, NY 10022			SHAHNAN SHAH, KHATOL S	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/600,564

Applicant(s)

KERN ET AL.

Examiner

Khatol S Shahnan-Shah

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 14 July 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: NONE.Claim(s) objected to: NONE.Claim(s) rejected: 14-21.Claim(s) withdrawn from consideration: 22-26.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

*Attachment to Advisory Action*

1. Applicants' reply to a final office action under 37 CFR 1.116, received 7/14/04 is acknowledged.
2. Claims 14-26 are pending in the application.
3. Claims 14-21 are under consideration. Claims 22-26 are withdrawn from consideration as being drawn to non-elected inventions.

*Status of Claims and Informalities*

4. Listing of the claims submitted 7/14/04 does not recite status of claims 25 and 26. These claims are withdrawn from consideration. Therefore, their status should be noted as "withdrawn" when the claims are listed. Appropriate corrections are required.

*Rejections Maintained*

5. Rejection of claims 14-21 under 35 USC § 102(b) made in paragraph 17 of the office action mailed 9/09/2003 is maintained.

The rejection was as stated below:

Claims 14-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Woitas et al. (Journal of Immunology of Immunology, Vol. 159, No. 2, pp. 1012-1018, 1997).

Claims are drawn to a method for identification of T-cell stimulating protein fragments comprising the following steps:

- detecting an amino acid sequence of an antigen;
- subdividing the amino acid sequence into fragments;
- synthesizing at least one protein fragment;
- incubating a suspension containing T-cells with the protein fragment;

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- identifying an induced T-cell cytokine or activation of a marker by flow cytometry;
- assigning experimental runs in which T-cells have been stimulated and the stimulation has been recognized by a T-cell cytokine or an activation marker.

Woitak et al. teach a method for identification of T-cell stimulating protein fragments comprising the following steps:

- detecting an amino acid sequence of an antigen;
- subdividing the amino acid sequence into fragments;( see page 1013, column 1, paragraphs 8-9)
- synthesizing at least one protein fragment; (see page 1013)
- incubating a suspension containing T-cells with the protein fragment; (see page 1013, column 2, paragraph 2)
- identifying an induced T-cell cytokine or activation of a marker by flow cytometry; (see page 1013, column 2, paragraph 3)
- assigning experimental runs in which T-cells have been stimulated and the stimulation has been recognized by a T-cell cytokine or an activation marker.

( see page 1013 , column 2, paragraph 3).

Woitak et al. describe the induction of CD30 and cytokines as a result of the HCV core protein or fragments thereof (see page 1013, column 1, paragraphs 8-9) acting on peripheral mononuclear cells of hepatitis patients (see abstract, pages 1013, 1014 and 1015). The peptides are incubated with cells (page 1013). The protein fragments essentially bound to MHC (page 1012). The T-cell cytokines such as, for example IL-2 and  $\text{INF}\gamma$ (see page 1014) undergo flow cytometry and therefore are identified as individual cell level (see page 1013 and 1014). The T-

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cell stimulation of both the protein fragments used are 25 amino acids long, and the control peptide is evaluated, i.e. protein fragments are allocated to T-cell stimulation (see figures 2 and 3 in page 1016 and page 1017). Woitas et al. teach both long and short incubation times. Woitas et al. teach long incubation time up to 40 hours (see page 13, column 2, paragraph 2) and short incubation time such as 30 minutes (see page 13, column 2, paragraph 3). The prior art anticipates the claimed invention.

Applicants' arguments filed 7/14/04 have been fully considered but they are not persuasive.

Applicants argue " A key element of the claimed method is that the incubation of T-cells with antigen is performed for a period of time that was much shorter than previously known in the art.

It is the examiner's position that Woitas et al. describe the induction of CD30 and cytokines as a result of the HCV core protein or fragments thereof (see page 1013, column 1, paragraphs 8-9) acting on peripheral mononuclear cells of hepatitis patients (see abstract, pages 1013, 1014 and 1015). The peptides are incubated with cells (page 1013). The protein fragments essentially bound to MHC (page 1012). The T-cell cytokines such as, for example IL-2 and INF $\gamma$  (see page 1014) undergo flow cytometry and therefore are identified as individual cell level (see page 1013 and 1014). The T-cell stimulation of both the protein fragments used are 25 amino acids long, and the control peptide is evaluated, i.e. protein fragments are allocated to T-cell stimulation (see figures 2 and 3 in page 1016 and page 1017). Woitas et al. teach both long and short incubation times. Woitas et al. teach long incubation time up to 40 hours (see page 13, column 2, paragraph 2) and short incubation time such as 30 minutes (see page 13, column 2,

paragraph 3). The claimed invention step (f) claim 14 recites the function limitations or phrases "sufficiently long", "sufficiently taken up" and "sufficiently short" which do not define a specific time limit for the incubation of the cells. The specification does not define or set metes and bounds of these periods therefore in absence of evidence to the contrary *Woitas et al.* teaches both long and short incubation periods and anticipates the claimed invention.

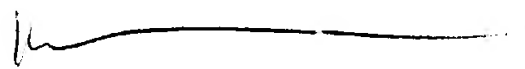
### *Conclusion*

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shahnan-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on 7:30am-4 pm.

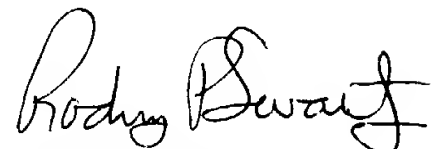
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith can be reached on (571)-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner, Art Unit 1645, September 20, 2004

  
RODNEY P SWARTZ, PH.D  
PRIMARY EXAMINER